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Public Health Service
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94102-7070
Telephone: 510-337-6700

Federal Express

Reference: 29-51509

November 9, 1998

Gerald W. Brouwer
Crestview Calf Ranch
3275 8th Avenue
Hanford, California 93230

WARNING LETTER

Dear Mr. Brouwer:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on October 13/15, 1998, by Food and Drug Administration (FDA) Investigator Robert J. Anderson have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On August 7, 1998, you sold a bob veal calf (identified by USDA laboratory report number 283320) for slaughter as human food. This calf was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this calf revealed gentamicin sulfate in the kidney at 7.60 parts per million (ppm). The tolerance level for gentamicin sulfate for the edible tissues of cattle is 0.00 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their species or class.

4. You lack an adequate system for assuring that drugs are used in am manner not contrary to the directions contained in their labeling.

5. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug rm (Rhone Merieux) brand of Gentamicn Sulfate within the meaning of Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(v) and is unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with its approved labeling. Your veterinarian prescribed the gentamicin sulfate for treatment of pneumonia and scours in calves only, and the prescribed labeling requires a withdrawal time of eighteen months. Treating calves with gentamicin sulfate, coupled with a failure to adhere to the recommended withdrawal time, is likely the cause of the presence of violative levels of gentamicin sulfate in the tissue of the animal you sold for food use.

Your use of the drug Pen G brand of penicillin G procaine is not in conformance with its approved labeling or your veterinarians drug protocol. The labeling for Pen G prescribes an intermuscular route of administration only and a dosage of 1 mL per 100 pounds of body weight and your veterinarians drug protocol prescribes a maximum of 7 cc per head per day. Your practice of administering 8 mLs to your calves in an intermuscular injection is an unapproved use for which safety and efficacy have not been established.

Your use of the drug NeoSol brand of Neomycin Sulfate Soluble Powder is not in conformance with its approved labeling. The labeling for NeoSol prescribes a maximum amount of 1000mg per head per day in one gallon of milk. Your practice of mixing three pounds of NeoSol into 200 gallons of milk and then giving one gallon of the mixture to each calf results in approximately 3,400 mg per head per day.

Failure to adhere to the labeling directions on the drugs you use to treat you cattle presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrections now may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Robert J. Anderson, Investigator, 2202 Monterey Street, Suite 104E, Fresno, California 93721.

Sincerely yours,

Patricia C. Ziobro

Patricia C. Ziobro
District Director
San Francisco District

cc: James P. Reynolds, DVM, MPVM
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